UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/900,559	07/25/1997	SHU-CHING CHENG	226/242	8245

22249 7590 12/19/2001

LYON & LYON LLP
633 WEST FIFTH STREET
SUITE 4700
LOS ANGELES, CA 90071

EXAMINER
HINES, JANA A

ART UNIT	PAPER NUMBER
1645	27

DATE MAILED: 12/19/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/900,559	CHENG ET AL	
	Examiner	Art Unit	
	Ja-Na A Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 October 2001* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Amendment Entry

1. The amendment filed October 1, 2001 has been entered. Claim 21 has been added. Claims 10-21 are under consideration in this Office Action.

Drawings

2. Applicant is required to submit a proposed drawing correction in reply to this Office action. However, formal correction of the noted defect can be deferred until the application is allowed by the examiner.

Withdrawal of Rejections

3. The following rejections are withdrawn in view of applicant's arguments:

a) the rejection of claims 10-20 under 35 U.S.C. 112, first paragraph.

b) the rejection of claims under 35 U.S.C. 102(b) as being anticipated by Imrich et al.

c) the rejection of claims 12 and 16 under 35 U.S.C. 103(a) as being unpatentable over Imrich et al., in view of Bogart et al.

Response to Arguments

4. Applicant's arguments with respect to claims 1-21 have been considered but are moot in view of the new grounds of rejection.

New Grounds For Rejection

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 10-11, 13-15 and 17-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Imrich et al., in view of Hochstrasser (US Patent 4,059,407). Imrich et al., teach a lateral flow medical diagnostic assay device with sample extraction means. The device comprises an extraction chamber; a labeling zone; a matrix that defines a flow path; a sample-receiving zone; and a capture zone (col. 3 lines 48-53). The extraction chamber allows for pretreatment of a sample generally presented on a swab (col. 3 lines 60-66). The extraction solution may added to the chamber, and may be treated with an acidic extraction solution such as nitrous acid to expose Group A streptococcus specific antigen (col. 4 lines 15-20). The extraction solution may contain nitrous acid that is relatively unstable, as a result, to generate nitrous acid, sodium nitrite and acetic acid must be mixed immediately before initiation of the antigen extraction process (col. 8 lines 50-63). In one example an equal volume of 1M sodium nitrite and 1M acetic acid was applied as the extraction solution and the swab was fully rotated in the extraction chamber (col. 11 lines 49-53). This assay device is capable of non-bibulous flow using a matrix material such as a manufactured membrane with open pore structure (col. 4 lines 25-63). The matrix comprises at least two zones, a sample

receiving zone and a capture zone (col. 4 lines 64-66). The sample-receiving zone may contain a neutralizing agent that will neutralize the extraction solution and may be placed on the surface of the sample-receiving zone (col. 5 lines 1-7). The labeling zone is present on the matrix and is between the sample receiving zone and the capture zone (col. 5 lines 9-13). The labeling means will generally be a labeled immunoglobulin, such as an antibody specific for the target analyte (col. 5 lines 15-26). As the treated sample flows through the labeling zone, the target analyte in the sample binds the labeled antibody thereby indirectly labeling the target antibody and then the sample continues its flow through into the capture zone where labeled target analyte is immobilized in the capture zone labeled target analyte will bind the immobilized immunoglobulins thereby retaining label in the capture zone (col. 5 lines 45-50). The presence of analyte will be determined by visual identification of label retention in the capture zone (col. 5 lines 50-52). The control procedure line is located downstream of the capture zone and retention of the label by the control procedural line indicates that the sample has flowed through the capture zone and contacted the immobilized target specific binding substance (col. 5 lines 58-60). The assay may include a pH indicating agent where a neutralized extraction solution will convert the end of assay indicator from bright yellow to blue (col. 6 lines 26-43). The component may contain two plastic removable pieces, the top piece contains the sample processing feature, the bottom piece is used for strip placement (col. 7 lines 37-41). Filters may be placed in the extraction chamber to remove particulate matter (col. 7 lines 42-48). The examples found at col. 10 line 10, explicitly describes detection of Group A streptococcus by means of a lateral flow assay

using a nitrous acid extraction solution made in equal volumes of 1M sodium nitrate and 1M acetic acid. However, Imrich et al., does not teach dipping the device into another chamber.

Hochstrasser teaches a dipstick device that can be immersed in a biological fluid to semi-quantitate analyte in the fluid. The device operates by immersion. The device comprises a support member, a plurality of indicating agents and separate zones (col. 2 lines 43-47). The instrument is immersed and removing the instruments allows reading of the indicated concentration (col. 2 lines 51-56). The device can be used with any biological fluid (col. 3 lines 17-19). Preferred materials are bibulous materials that may be impregnated with reagent compositions (col. 3 lines 65-68).

Therefore, no more than routine skill would have been required to incorporate the well known immersion method as taught by Hochstrasser into the method of determining the presence or absence of Streptococcus Group A antigen in a sample as taught by Imrich et al., since Hochstrasser teaches that it is well known in the art to use immersion methods to detect an antigen.

6. Claims 12 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Imrich et al., and Hochstrasser in view of Bogart et al. Imrich et al., and Hochstrasser have been previously discussed, however neither teaches the vigorous mixing or an extraction solution where the addition of the extraction materials are of similar concentrations. Bogart et al., teaches extraction methods for Group A streptococcus (col. 6 lines 10-18). Bogart et al., teaches a standard nitrous acid extraction method as being a mixture of 0.25M acetic acid and 2.3M sodium nitrate to

generate nitrous acid. Antigen is extracted from the organism for 5 minutes, although the range is instantaneous to 30 minutes. Further, the solution is neutralized using a buffer. (col. 10-11).

Therefore, it would have been obvious to one of ordinary skill in the art to optimize the experimental parameters and reagents of the method of Imrich et al., and Hochstrasser by selecting such conventional components for generating nitrous acid and times of extraction as taught by Bogart et al., where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is (703) 305-0487. The examiner can normally be reached on Monday through Thursday from 6:30am to 4:00pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Ja-Na Hines
December 16, 2001

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600